MAY 2 4 2000

GE Marquette Medical Systems

Section C - 510(k) Summary

February 24, 2000

A. Contact Information:

Ian McDonald
Regulatory Associate
GE Marquette Medical Systems
13000 Executive Drive
Sugar Land, TX 77478

Phone: (281) 275-5109
Fax: (281) 275-5001

B. Device names:

Trade Name: GE Marquette Medical Systems Prucka CardioLab Cath System
Common Name: Catheterization lab system
Classification Names:

870.2340	Electrocardiograph (DPS, Class II, 74 CV)
870.2050	Biopotential Amplifier and Signal Conditioner (DRR, Class II, 74 CV)
870.1425	Programmable Diagnostic Computer (DQK, Class II, 74 CV)
870.1110	Blood Pressure Computer (DSK, Class II, 74 CV)

C. Substantial equivalence is claimed to the following devices:

Prucka Engineering CardioCath Catheterization Lab System (K960321)
GE Marquette Medical Systems Mac-Lab System (K992948)

D. Description of device:

The Prucka CardioLab Cath System is a microprocessor based data acquisition system used during cath lab procedures to acquire ECG, intracardiac and pressure data. Digital data from other devices typically used during cath lab procedures may also be acquired by the Prucka CardioLab Cath System via standard RS-232 serial port of the computer. The ECG, intracardiac and pressure data is acquired by an amplifier that is connected to the patient by third-party devices such as ECG leadwires and catheters. The amplifier filters, amplifies, digitizes and transmits the data to the computer. The computer stores the data on optical disks, displays the data on the video monitors, allows the user to perform basic signal measurements, and prints out waveforms on a laser printer or continuous paper recorder. The software has three major

components: data acquisition and display, data storage, and reporting of data. The Prucka CardioLab Cath system does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze physiological data or other data acquired during a cath procedure. It does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.

E. Intended use of device:

The intended use of the GE Marquette Medical Systems Prucka CardioLab Cath System is to acquire, filter, digitize, amplify, display, and record electrical signals obtained during cardiac catheterization studies and related procedures conducted in a cardiac catheterization laboratory. Signal types acquired include ECG signals, direct cardiac signals, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. Additionally, the system may acquire, amplify, display, and record data received from other medical devices typically used during these procedures, such as noninvasive blood pressure, pulse oximetry, cardiac output, respiration, temperature, and whole blood oximetry.

F. Summary of the technological characteristics of the Prucka CardioLab Cath System compared to the predicate devices:

As indicated in Section F of this submission, technological characteristics of the proposed Prucka CardioLab Cath System version 1.11 are the same as the original cleared Prucka CardioCath Catheterization Lab System (K960321). The proposed device has the ability to display data from other devices typically used in Cath Lab procedures, which is a new feature in this device, but this does not change the fundamental technology of the device as compared to the original cleared device. The display of this information, including noninvasive blood pressure, pulse oximetry, cardiac output, respiration, temperature, and whole blood oximetry, is redundant to the physiologic devices' own display of the same information, and is in accordance with specifications of the physiologic devices which output the data intended for such purpose. The proposed device also includes a new LAN option which allows alpha-numeric data to be exported to a hospital information system for storage. The addition of a LAN option is for customer convenience, does not change the intended use of the device, and raises no new issues of safety and efficacy.

Technological characteristics of the proposed Prucka CardioLab Cath System version 1.11 are not significantly different from the GE Marquette Mac-Lab System (K992948) as indicated in Section F of this submission. The Mac-Lab System includes the ability to interface with physiologic devices to display

information such as noninvasive blood pressure, pulse oximetry, cardiac output, respiration, temperature, and whole blood oximetry. The Mac-Lab System also includes LAN options which allow data to be exported to hospital information systems for storage.

The comparison of the Prucka CardioLab Cath System device and the predicate devices in Section F of this submission raises no new issues of safety and efficacy. Each characteristic of the CardioLab Cath System is found in at least one predicate device used in the same type of procedure as the CardioLab Cath System is intended to be used in. No new uses are introduced by the proposed device as compared to the predicate devices. Therefore the proposed Prucka CardioLab Cath System device is substantially equivalent to the aforementioned predicate devices.

G. Brief discussion of the nonclinical tests and how their results support a determination of substantial equivalence:

The equipment has been tested and certified to meet the following national and international safety standards by SEMKO which is an Inchcape Testing Services Company.

IEC 601-1
IEC 601-1-1
IEC 601-1-2
IEC 601-2-27
IEC 601-2-34

The equipment has also been tested by ETL Testing Laboratories with the applicable requirements of the FDA Reviewer Guidance for premarket Notification Submissions, November 1993.

In addition, an in-house validation has been performed on the system with results that meet acceptance criteria, confirming the safety and efficacy of each functional aspect of the system.

These tests conducted by outside laboratories together with system level validation testing conducted in-house provide complete confirmation that the system is safe and effective for its intended use. This demonstrates that the Prucka CardioLab Cath System has a substantially equivalent level of safety and efficacy as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2000

GE Marquette Medical Systems, Inc.
C/O Ian McDonald, Regulatory Associate
13000 Executive Drive
Sugar Land, TX 77478

Re: K000645
Trade Name: GE Marquette Prucka CardioLab Cath System (Version 1.1)
Regulatory Class: II
Product Code: DPS
Dated: February 24, 2000
Received: February 25, 2000

Dear Mr. McDonald:

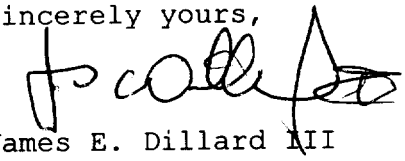
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000645

Device Name: Prucka CardioLab Cath System, Version 1.11

Indications for Use:

The intended use of the GE Marquette Medical Systems Prucka CardioLab Cath System is to acquire, filter, digitize, amplify, display, and record electrical signals obtained during cardiac catheterization studies and related procedures conducted in a cardiac catheterization laboratory. Signal types acquired include ECG signals, direct cardiac signals, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. Additionally, the system may acquire, amplify, display, and record data received from other medical devices typically used during these procedures, such as noninvasive blood pressure, pulse oximetry, cardiac output, respiration, temperature, and whole blood oximetry.

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Concurence of CDRH, Office of Device Evaulation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000645

(Optional Format 3-10-98)